

Claims

1. A method for the prevention of dysglucaemia in humans, the method involving a minimal supply of calories, **characterized** in that a predetermined amount of starch is administered orally to the human in granulated form having a reduced surface available for enzymatic degradation, which granulation delays the enzymatic degradation of the starch into reducing sugars to a duration and level, adjusted to the metabolism of the patient.
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2. A method for the long term prevention of nocturnal and/or morning hypoglycaemia in patients suffering from diabetes, including both IDDM and NIDDM, **characterized** in that a predetermined amount of starch is administered orally to the patient in granulated form, which
10 granulation delays the enzymatic degradation of the starch into reducing sugars to a duration and level, adjusted to the metabolism of the patient.
3. A method for effective glycaemic control in diabetic patients, the method involving a minimal supply of calories, **characterized** in that a predetermined amount of starch is administered orally to the human in granulated form having a reduced surface available for
15 enzymatic degradation, which granulation delays the enzymatic degradation of the starch into reducing sugars to a duration and level, adjusted to the metabolism of the patient.
4. A method according to claim 1, **characterized** in that the humans are patients scheduled to undergo surgical or invasive medical treatment.
5. A method according to claim 1, **characterized** in that the humans are diabetic patients
20 scheduled for surgical or invasive medical treatment.
6. A method according to claim 1, **characterized** in that the humans are suffering from a chronic disease, such as a disease chosen among: viral infections, liver disease, hepatitis, alcohol abuse, cancer, HIV, AIDS or a combination thereof.
7. A method according to claim 1, **characterized** in that the humans are patients on post-
25 operative medication, having undergone surgical or invasive treatment.
8. A method according to any one of claims 4 – 7, **characterized** in that the treatment is given in conjunction to insulin treatment.

9. A method according to claim 5, characterized in that the treatment is given in conjunction to insulin treatment.

10. A method according to claim 6, characterized in that the treatment is given in conjunction to insulin treatment.

5 11. A method according to claim 7, characterized in that the treatment is given in conjunction to insulin treatment.

12. A method according to claim 1, **characterized** in that the humans are athletes training or participating in an endurance sport, such as long distance running, long distance skiing or long distance skating.

10 13. The method according to claims 1, **characterized** in that the starch is native cornstarch.

14. A method according to claim 2, **characterized** in that the humans are athletes training or participating in an endurance sport, such as long distance running, long distance skiing or long distance skating.

15 15. A method according to claim 3, **characterized** in that the humans are athletes training or participating in an endurance sport, such as long distance running, long distance skiing or long distance skating.

16. A method according to claim 4, **characterized** in that the humans are athletes training or participating in an endurance sport, such as long distance running, long distance skiing or long distance skating.

20 17. A method according to claim 5, **characterized** in that the humans are athletes training or participating in an endurance sport, such as long distance running, long distance skiing or long distance skating.

25 18. A method according to claim 6, **characterized** in that the humans are athletes training or participating in an endurance sport, such as long distance running, long distance skiing or long distance skating.

19. A method according to claim 7, **characterized** in that the humans are athletes training or participating in an endurance sport, such as long distance running, long distance skiing or long distance skating.

20. A method according to claim 8, **characterized** in that the humans are athletes training or participating in an endurance sport, such as long distance running, long distance skiing or long distance skating.

21. A method according to claim 12, **characterized** in that the humans are athletes training or participating in an endurance sport, such as long distance running, long distance skiing or long distance skating.

22. The method according to claim 1, **characterized** in that the starch is encapsulated in a substance chosen among gum arabicum, potassium alginate, guar gum, methyl cellulose, ethyl cellulose; liquid oils, liquid and hard fats and waxes, such as paraffin, hydrogenated cottonseed oil, beeswax, and carnauba wax.

23. The method according to claim 2, **characterized** in that the starch is encapsulated in a substance chosen among gum arabicum, potassium alginate, guar gum, methyl cellulose, ethyl cellulose; liquid oils, liquid and hard fats and waxes, such as paraffin, hydrogenated cottonseed oil, beeswax, and carnauba wax.

24. The method according to claim 3, **characterized** in that the starch is encapsulated in a substance chosen among gum arabicum, potassium alginate, guar gum, methyl cellulose, ethyl cellulose; liquid oils, liquid and hard fats and waxes, such as paraffin, hydrogenated cottonseed oil, beeswax, and carnauba wax.

25. The method according to claim 4, **characterized** in that the starch is encapsulated in a substance chosen among gum arabicum, potassium alginate, guar gum, methyl cellulose, ethyl cellulose; liquid oils, liquid and hard fats and waxes, such as paraffin, hydrogenated cottonseed oil, beeswax, and carnauba wax.

26. The method according to claim 5, **characterized** in that the starch is encapsulated in a substance chosen among gum arabicum, potassium alginate, guar gum, methyl cellulose, ethyl cellulose; liquid oils, liquid and hard fats and waxes, such as paraffin, hydrogenated cottonseed oil, beeswax, and carnauba wax.

27. The method according to claim 6, **characterized** in that the starch is encapsulated in a substance chosen among gum arabicum, potassium alginate, guar gum, methyl cellulose, ethyl

cellulose; liquid oils, liquid and hard fats and waxes, such as paraffin, hydrogenated cottonseed oil, beeswax, and carnauba wax.

28. The method according to claim 7, **characterized** in that the starch is encapsulated in a substance chosen among gum arabicum, potassium alginate, guar gum, methyl cellulose, ethyl
5 cellulose; liquid oils, liquid and hard fats and waxes, such as paraffin, hydrogenated cottonseed oil, beeswax, and carnauba wax.

29. The method according to claim 8, **characterized** in that the starch is encapsulated in a substance chosen among gum arabicum, potassium alginate, guar gum, methyl cellulose, ethyl cellulose; liquid oils, liquid and hard fats and waxes, such as paraffin, hydrogenated
10 cottonseed oil, beeswax, and carnauba wax.

30. The method according to claim 12, **characterized** in that the starch is encapsulated in a substance chosen among gum arabicum, potassium alginate, guar gum, methyl cellulose, ethyl cellulose; liquid oils, liquid and hard fats and waxes, such as paraffin, hydrogenated cottonseed oil, beeswax, and carnauba wax.

- 15 31. The method according to claim 1, **characterized** in that the starch is encapsulated in ethyl cellulose.

32. The method according to claim 2, **characterized** in that the starch is encapsulated in ethyl cellulose.

- 20 33. The method according to claim 3, **characterized** in that the starch is encapsulated in ethyl cellulose.

34. The method according to claim 4, **characterized** in that the starch is encapsulated in ethyl cellulose.

35. The method according to claim 5, **characterized** in that the starch is encapsulated in ethyl cellulose.

- 25 36. The method according to claim 6, **characterized** in that the starch is encapsulated in ethyl cellulose.

37. The method according to claim 7, **characterized** in that the starch is encapsulated in ethyl cellulose.

38. The method according to claim 8, **characterized** in that the starch is encapsulated in ethyl cellulose.

39. The method according to claim 12, **characterized** in that the starch is encapsulated in ethyl cellulose.

5 40. The method according to claim 1, **characterized** in that the enzymatic degradation is delayed to an extent resulting in a linear release of reducing sugars for more than 4 hours, preferably more than 6 hours, most preferably about 8 hours.

41. The method according to claim 2, **characterized** in that the enzymatic degradation is delayed to an extent resulting in a linear release of reducing sugars for more than 4 hours,
10 preferably more than 6 hours, most preferably about 8 hours.

42. The method according to claim 3, **characterized** in that the enzymatic degradation is delayed to an extent resulting in a linear release of reducing sugars for more than 4 hours, preferably more than 6 hours, most preferably about 8 hours.

43. The method according to claim 4, **characterized** in that the enzymatic degradation is
15 delayed to an extent resulting in a linear release of reducing sugars for more than 4 hours, preferably more than 6 hours, most preferably about 8 hours.

44. The method according to claim 5, **characterized** in that the enzymatic degradation is delayed to an extent resulting in a linear release of reducing sugars for more than 4 hours, preferably more than 6 hours, most preferably about 8 hours.

20 45. The method according to claim 6, **characterized** in that the enzymatic degradation is delayed to an extent resulting in a linear release of reducing sugars for more than 4 hours, preferably more than 6 hours, most preferably about 8 hours.

46. The method according to claim 7, **characterized** in that the enzymatic degradation is delayed to an extent resulting in a linear release of reducing sugars for more than 4 hours,
25 preferably more than 6 hours, most preferably about 8 hours.

47. The method according to claim 8, **characterized** in that the enzymatic degradation is delayed to an extent resulting in a linear release of reducing sugars for more than 4 hours, preferably more than 6 hours, most preferably about 8 hours.

48. The method according to claim 12, **characterized** in that the enzymatic degradation is delayed to an extent resulting in a linear release of reducing sugars for more than 4 hours, preferably more than 6 hours, most preferably about 8 hours.

49. A composition for delayed enzymatic degradation of starch in the gastrointestinal tract of a mammal, **characterized** in that said composition contains an optimal and minimised granulated starch, the degree of granulation being adapted to the desired enzymatic degradation rate of said starch, a low calorie sweetener and an organic acid.

50. The composition according to claim 49, **characterized** in that the starch is native cornstarch.

51. The composition according to claim 49, **characterized** in that the starch is granulated and at least partially encapsulated in a substance chosen among gum arabicum, potassium alginate, guar gum, methyl cellulose, ethyl cellulose; liquid oils, liquid and hard fats and waxes, such as paraffin, hydrogenated cottonseed oil, beeswax, and carnauba wax.

52. The composition according to claim 49, **characterized** in that the starch is granulated and at least partially encapsulated in ethyl cellulose.

53. The composition according to claim , **characterized** in that the enzymatic degradation is delayed to an extent resulting in a controlled, substantially linear glucose release for more than 4 hours, preferably more than 6 hours, most preferably more than 8 hours.

54. A composition for delayed degradation of starch, **characterized** in that said composition comprises

- about 60 - 90 % by weight granulated native cornstarch,
- 0.01 – 25 % by weight of a low calorie sweetener.

55. The composition according to claim 54, **characterized** in that the native cornstarch is granulated with ethyl cellulose.

56. The composition according to claim 54, further comprising an organic acid.

57. A method for production of a composition for delayed degradation of starch, **characterized** in that the method comprises the following steps:

- wet granulation of native cornstarch with a substance,
 - wet sieving and drying of the granulated starch,
 - adding a low calorie sweetener, an organic acid and optionally unsaturated fat to the mixture, and
- 5 - pressing the mixture into tablets.
58. A method for production of a composition for delayed degradation of starch, **characterized** in that the method comprises the following steps:
- wet granulation of native cornstarch with a substance,
 - wet sieving and drying of the granulated starch,
- 10 - adding a low calorie sweetener, an organic acid and optionally unsaturated fat to the mixture, and
- weighing and packing the granulated formulation for storage and/or delivery.
59. The method according to claim 56, **characterized** in that the substance is chosen among gum arabicum, potassium alginate, guar gum, methyl cellulose, ethyl cellulose, liquid oils,
- 15 liquid and hard fats and waxes, such as paraffin, hydrogenated cottonseed oil, beeswax, and carnauba wax.
60. The method according to claim 57, **characterized** in that the substance is chosen among gum arabicum, potassium alginate, guar gum, methyl cellulose, ethyl cellulose, liquid oils,
- 20 liquid and hard fats and waxes, such as paraffin, hydrogenated cottonseed oil, beeswax, and carnauba wax.
61. The method according to claim 56, **characterized** in that the substance is ethyl cellulose.
62. The method according to claim 57, **characterized** in that the substance is ethyl cellulose.
63. The method according to claim 56, **characterized** in that the organic acid is one of ascorbic acid, malic acid and citric acid.
- 25 64. The method according to claim 57, **characterized** in that the substance is ethyl cellulose.